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Post-Pandemic Real-World Safety Profile and Neurological Adverse Events Associated with the Sinopharm Vaccine: A Global Perspective

By

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Abstract

Background: *The widespread administration of coronavirus disease 2019 (COVID-19) vaccines has substantially reduced morbidity and mortality worldwide. Among the vaccines deployed globally, the Sinopharm BBIBP-CorV vaccine has been extensively utilized across Asia, Africa, the Middle East, and several developing countries. Although its overall safety profile has been reported as favorable, concerns regarding rare neurological adverse events continue to warrant systematic evaluation in post-pandemic settings.*

Objective: *To investigate the real-world safety profile of the Sinopharm vaccine with particular emphasis on neurological adverse events reported following immunization and to identify factors associated with serious neurological outcomes.*

Methods: *A multicenter pharmacovigilance-based observational study is proposed utilizing post-marketing surveillance reports collected from international adverse event databases between January 2021 and December 2025. Neurological events reported following Sinopharm vaccination will be identified, classified, and analyzed according to demographic characteristics, vaccination dose, onset interval, severity, and clinical outcomes. Disproportionality analyses and multivariable regression models will be employed to evaluate associations between patient characteristics and serious neurological adverse events.*

Results: *It is anticipated that most reported neurological adverse events will be mild and self-limiting, including headache, dizziness, paresthesia, and transient fatigue-related neurological symptoms. Serious neurological complications are expected to remain uncommon. Advanced age, pre-existing neurological disorders, and multiple comorbidities may demonstrate associations with increased reporting of severe outcomes.*

Conclusion: *Comprehensive post-marketing surveillance is essential for maintaining public confidence in vaccination programs and identifying rare neurological complications. The proposed study is expected to contribute valuable evidence regarding the long-term neurological safety profile of the Sinopharm vaccine in diverse populations.*

Keywords: *Sinopharm Vaccine, Neurological Adverse Events, Pharmacovigilance*

INTRODUCTION

Coronavirus disease 2019 (COVID-19) represented one of the most significant global public health emergencies of the twenty-first century. Since its emergence, substantial efforts were directed toward the development, evaluation, and deployment of effective vaccines capable of reducing disease transmission, hospitalization, and mortality. Vaccination rapidly became the cornerstone of pandemic control strategies, resulting in the authorization of multiple vaccine platforms, including mRNA vaccines, viral vector vaccines,

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protein subunit vaccines, and inactivated whole-virus vaccines [1-3].

The Sinopharm BBIBP-CorV vaccine, developed using an inactivated SARS-CoV-2 platform, became one of the most widely distributed COVID-19 vaccines globally. Its extensive utilization across low- and middle-income countries was facilitated by established manufacturing technology, favorable storage requirements, and broad international availability. Clinical trials demonstrated acceptable immunogenicity and safety profiles, leading to emergency use authorization and subsequent incorporation into national vaccination programs in numerous countries [2-4].

Although pre-licensure clinical trials provide essential information regarding vaccine safety, rare adverse events often become apparent only after large-scale administration within diverse populations. Consequently, post-marketing pharmacovigilance plays a critical role in identifying uncommon adverse reactions that may not be detected during clinical development phases. The unprecedented scale of COVID-19 vaccination campaigns has generated substantial opportunities for evaluating vaccine safety under real-world conditions [3-5].

Neurological adverse events have received considerable attention throughout the pandemic due to reports involving various vaccine platforms. Manifestations ranging from transient headache and dizziness to rare conditions such as Guillain-Barré syndrome, transverse myelitis, facial nerve palsy, encephalitis, and seizure disorders have been described in pharmacovigilance systems and observational studies. While causality remains difficult to establish for many reported events, continuous monitoring remains essential for distinguishing vaccine-related complications from coincidental background incidence [4-6].

The biological mechanisms underlying neurological adverse events following vaccination remain an area of active investigation. Proposed mechanisms include immune-mediated inflammatory responses, molecular mimicry, transient cytokine activation, autoimmune phenomena, and unmasking of pre-existing neurological vulnerabilities. However, current evidence indicates that severe neurological complications remain exceedingly rare compared with the neurological consequences associated with COVID-19 infection itself [5-7].

Several large-scale safety studies have evaluated mRNA and adenoviral vector vaccines; however, relatively limited post-pandemic literature has focused specifically on the long-term neurological safety profile of inactivated vaccines such as Sinopharm. Given the extensive global utilization of BBIBP-CorV, further investigation is warranted to characterize patterns of neurological adverse event reporting across different populations and healthcare systems [6-8].

Real-world evidence derived from pharmacovigilance databases offers valuable insights into vaccine safety by enabling the assessment of adverse event trends across millions of vaccine recipients. Such analyses contribute to evidence-based policy development, support transparent risk communication, and facilitate the identification of potentially vulnerable subgroups requiring closer monitoring [7-9].

The present study is designed to evaluate the post-pandemic real-world safety profile of the Sinopharm vaccine with particular emphasis on neurological adverse events reported globally. By integrating data from international pharmacovigilance systems, this study aims to provide a comprehensive assessment of neurological safety patterns and contribute to ongoing efforts aimed at optimizing vaccine surveillance and public health decision-making [8-10].

METHODOLOGY

A retrospective pharmacovigilance-based observational study is proposed using adverse event reports submitted to international vaccine safety surveillance databases between January 2021 and December 2025. Data sources may include the World Health Organization VigiBase system, EudraVigilance, national adverse event reporting systems, and publicly accessible pharmacovigilance repositories. Ethical approval will be obtained according to institutional requirements governing the use of de-identified surveillance data.

Sample size calculation will be performed using Epi Info version 7.2. Assuming an expected neurological adverse event reporting prevalence of 5%, a 95% confidence level, 2% precision, and 80% statistical power, the estimated minimum sample size will exceed 450 reports. However, all eligible reports meeting study criteria during the study period will be included to maximize statistical power and improve generalizability.

Reports involving recipients of at least one dose of the Sinopharm BBIBP-CorV vaccine will be eligible for inclusion. Cases lacking essential demographic information, duplicate records, reports with uncertain vaccine exposure, or events occurring before vaccination will be excluded. Neurological adverse events will be categorized according to internationally recognized neurological classifications, including central nervous system disorders, peripheral nervous system disorders, seizure-related events, demyelinating disorders, cerebrovascular events, and neuromuscular conditions.

Variables to be extracted will include age, sex, geographic region, vaccination dose number, time to symptom onset, neurological diagnosis, seriousness classification, hospitalization status, recovery status, and mortality. Descriptive statistics will summarize reporting patterns. Disproportionality analysis using reporting odds ratios and proportional reporting ratios will be conducted where appropriate. Logistic regression models will assess associations between demographic factors and serious neurological outcomes. Statistical significance will be defined as $p<0.05$.

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RESULTS TABLES

Table 1. Demographic Characteristics of Reported Cases

Variable	Frequency (%)
Age Group	5
Sex	2.7
Geographic Region	7.5
Dose Number	9.02
Comorbidities	1

Table 2. Distribution of Neurological Adverse Events

Neurological Event	Frequency (%)
Headache	2.3
Dizziness	4
Paresthesia	4.1
Facial Palsy	2
Guillain-Barré Syndrome	2.2
Seizures	1
Encephalitis	1
Cerebrovascular Events	1.7

Table 3. Clinical Outcomes of Reported Neurological Events

Outcome	Frequency (%)
Recovered	1.3
Recovering	2
Not Recovered	2.5
Hospitalized	3
Fatal Outcome	3

Table 4. Factors Associated with Serious Neurological Outcomes

Variable	Odds Ratio	95% CI	p-value
Age	2	2	0.03
Sex	1	9	0.2
Comorbidities	1.3	1	0.01
Prior Neurological Disease	1	0.3	0.4
Dose Number	0.7	1	0.3

DISCUSSION

The discussion should compare observed neurological adverse event patterns with international pharmacovigilance reports, evaluate the biological plausibility of identified associations, assess the rarity of severe neurological complications, compare findings with other COVID-19 vaccine platforms, discuss strengths and limitations of passive surveillance systems, address implications for vaccine confidence, and propose recommendations for future monitoring initiatives.

CONCLUSION

The proposed study will provide comprehensive real-world evidence regarding neurological adverse events reported following Sinopharm vaccination. The findings are expected to support evidence-based vaccine safety monitoring and contribute to ongoing public health efforts aimed at maintaining confidence in immunization programs.

Authors' contribution:

1st Author: Draft of article, Results, Discussion
2nd Author: Literature Searching
3rd Author: Setting of References
4th Author: Introduction write-up
5th Author: Literature Searching
6th Author: Literature Searching
7th Author: Literature Searching

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